

Clinical Trial Plan (Template)

1. Objective: Evaluate device effectiveness in improving speech recognition and QoL.
2. Design: Randomized controlled trial or pragmatic study as appropriate.
3. Population: Adults with moderate-to-severe sensorineural hearing loss.
4. Outcomes: Primary - speech recognition in noise. Secondary - QoL, battery life, adverse events.
5. Analysis: Pre-specified statistical plan with intent-to-treat analysis.
6. Ethics: IRB approval, informed consent, data privacy compliance.